

REMARKS

Claims **1, 13-15, 18** and **22** are pending in the application.

New Rejections under 35 U.S.C. § 103(a)

Claims **1, 13-15, 18** and **22** are rejected under 35 U.S.C. § 103(a) as being unpatentable over the combination of Palmieri et al. (S.T.P. Pharma Sciences, 188-194 (1996)), and U.S. Patent 5,545,628 ('628). Applicants respectfully disagree.

It is well established law that the PTO has the burden under 35 U.S.C. §103 to establish a case of *prima facie* obviousness (In re Fine, 5 USPQ2d 1596, 1599 (Fed. Cir. 1988)). To satisfy this burden, an Examiner must identify both (i) a suggestion to modify a primary reference in accordance with the teachings of one or more secondary references to achieve the claimed invention and (ii) a reasonable expectation of success in making and using the modified procedure (In re Vaeck, 20 USPQ2d 1438, 1442 (Fed. Cir. 1991)). Furthermore, both the suggestion and the reasonable expectation of success must be founded in the prior art, not in the applicant's disclosure (In re Dow Chemical Co., 5 USPQ2d 1529, 1531 (Fed. Cir. 1988)). The modification must be more than just "obvious to try", which the Court of Appeals for the Federal Circuit has rejected as a standard for obviousness (In re O'Farrell, 7 USPQ2d 1673 (Fed. Cir. 1988)). Moreover, in combining references, the Examiner may not use an applicant's disclosure as a guide or template to select elements or features from among prior art references which, when assembled together, arrive at the claimed invention (In re Fritch, 23 USPQ2d 1780, 1784 (Fed. Cir. 1992)). Under these standards, Applicants respectfully contend that the combined teachings of Palmieri *et al.* and '628 fail to render Applicant's invention obvious.

The teachings of Palmieri et al. are directed to the preparation of a solid dispersion of fenofibrate in PEG 4000 using evaporation or fusion methods, in which reference it is explained that fenofibrate solubility is substantially increased by the solid dispersion formation. Palmieri *et al.* does not teach, suggests, or discuss the use of HPMC to improve the solubility of said fenofibrate solid dispersion.

The teachings of '628 are directed to a homogeneous fenofibrate solution of fenofibrate (Col. 2, lines 56-60). The final composition is maintained in liquid state and

capsules are filled with this liquid composition using a liquid filling capsule machine (Col. 4, lines 1-13). Fenofibrate is never re-solidified, therefore '625 does not teach or describes fenofibrate in solid state, as the claims of the present application do.

The Office Action states that it would have been obvious to one of skill in the art to prepare a fenofibrate composition based on the combinations of the teachings of Palmieri *et al.*, and '625. Applicants respectfully disagree as being a mere speculation laced with forbidden hindsight because Palmieri *et al.*, fails to provide the motivation or suggestion to use HPMC as a stabilizer for a liquid fenofibrate solution, and '625 does not teach a solid dispersion of fenofibrate.

In view of the foregoing remarks, Applicants submit that the Office Action has failed to present a *prima facie* case of obviousness. Applicants respectfully request favorable reconsideration of claims 1, 13-15, 18 and 22 and allowance of this application.

Claims 1, 13-15, 18 and 22 are rejected under 35 U.S.C. § 103(a) as being unpatentable over the combination of Palmieri *et al.* (S.T.P. Pharma Sciences, 188-194 (1996)), and U.S. Patent 6,465,011 ('011). Applicants respectfully submit evidence of common ownership in a separate document included in the present response. In the instant case the subject matter of the '011 patent and the claimed invention, were commonly owned by the same company at the time the invention of the present application was made, thus disqualifying the '011 patent as prior art cited against the invention. This leaves Palmieri *et al.*, as the only piece of prior art for this rejection. Applicants respectfully assert that Palmieri *et al.*, alone does not teach or suggest the subject matter of the present invention.

CONCLUSION

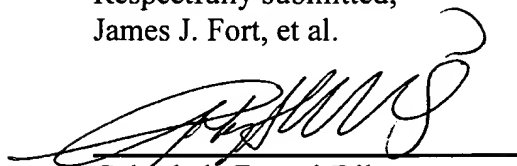
Applicants respectfully submit that the claims comply with all the requirements for patentable subject matter over the art. Accordingly a Notice of Allowance is respectfully requested.

If the Examiner notes any further matters that the Examiner believes can be

expedited by a telephone interview, the Examiner is respectfully requested to contact the undersigned.

Respectfully submitted,
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